

FULLY ELECTRONIC WRIST WATCH WITH TEMPERATURE
MEASUREMENT FACILITY FOR FAMILY PLANNING

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1. Objective

Millions of women all over the world take the oral contraceptive pill every day in order to prevent conception.

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Millions of women rely for the same reason on mechanical methods and in so doing run the risk of developing cancer.

On the other hand, millions of women want to have children and try for years to find the most favourable time to conceive.

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Both groups taken together represent a substantial proportion of the world's population (500 to 600 million women between 15 and 49 years of age capable of bearing children) and can be helped by the modern technical aid according to the invention.

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This is an electronic wrist watch with integrated microprocessor and permanent temperature measurement, which fulfils the following tasks:

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- a) measuring the skin temperature
- b) recording the measurement data
- c) processing the measurement data
- d) recommendations

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All four areas operate fully automatically, identify ovulation and at the right time output a recommendation, either digitally or acoustically.

Depending on the individual requirements, the ovulation thus detected can be a signal for abstinence (contraception) or can be exploited (conception).

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2. Medical principles

In sexually mature females, the physiological events in the endocrine glands take place at regular intervals (cycles).

A cycle ideally lasts 28 ± 3 days, ovulation taking place on the 14th day.

This total cycle is divided into the follicle phase, the duration of which varies, and the relatively
5 constant corpus luteum phase.

In the follicle phase, the egg matures to ovulation. Duration: 8 - 19 days.

In the corpus luteum phase, the endometrium (functional layer) is prepared such that the implanted
10 egg can be nourished. Duration: 10 - 18 days.

The total cycle ends with rejection of the functional layer (menstruation) if no fertilization has taken place.

The large individual variations in the duration
15 of the cycle are caused by psychological or environmental factors.

In most women, the duration of the cycle varies between 24 and 32 days. In individual cases, however, 21 to 48 days is also possible.

20 The sequences of events during the cycle are controlled by a series of hormones. Of particular importance is the LH release hormone (luteinizing hormone) whose secretion can be inhibited by psychological factors, for example anxiety.

25 This also explains the range of variation in the follicle phase because LH among other things controls the follicle maturation and ovulation.

The LH level in the plasma and in the urine is at its greatest shortly before ovulation. The same is
30 true for oestrogen release.

After ovulation, the rate of release of these hormones falls rapidly and corpus luteum production (progesterone) commences.

A woman's body temperature changes
35 synchronously with the respective hormone secretion.

This phenomenon is important for detecting ovulation, since precisely at this time there is a drop in temperature of about 0.3°C below the normal temperature of about 37°C . This drop is caused by the

oestrogen release, which has reached its maximum on the day preceding ovulation.

5 In the following 40 to 80 hours, the body temperature increases synchronously with the progesterone production, up to values which are likewise 0.3°C above the average internal body temperature. That is to say, the rise in temperature after the preceding temperature minimum clearly characterizes ovulation.

10 This also applies in cases of rhythm disturbances, with one exception: in oligomenorrhoea the temperature curve is below the mean line, with great variations forming a multiplicity of minima and maxima.

15 If we are now able to record this characteristic temperature course by means of an automatic temperature measurement, ovulation can be predicted and can be established as having taken place after the subsequent rise in temperature.

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3. Physiological principles of endogenous heat regulation

It has previously been possible to detect ovulation under clinical conditions, or with very disciplined measurements of the waking temperature over a number of cycles. Normally, the basal temperature in the rectum is measured using a clinical thermometer (5 minutes). This so-called internal body temperature is approximately 0.5°C above the orally measured temperature and $2-3^{\circ}\text{C}$ above the temperature at the periphery, i.e. the skin.

30 Body temperature is regulated by a cybernetic process aimed at achieving as constant as possible a body temperature. In this process, heat is produced by metabolic changes or by increased circulation and/or contraction of the muscles, depending on the reaction of the heat receptors in the skin. Heat is released by changes in circulation at the skin, by transpiration and by radiation and convection. The body tissue itself

has a high heat-binding capacity, so that latent heat can be stored therein with relatively low intrinsic heating.

5 The daily temperature profile shows a regularly recurring pattern with a minimum of 36.4°C during sleep at 5 a.m. to 6 a.m. and a maximum of 37.3°C in the afternoons.

Physical exertion, food intake, psychological agitation and alcohol consumption also lead to
10 temperature changes.

In women between 15 and 49 years of age and capable of bearing children, there are additionally the temperature fluctuations which occur during the menstrual cycle, caused by the release of hormones
15 already described.

In purely physical terms, the oestrogens cause a widening of the skin vessels, as a result of which the conduction and radiation of heat are increased and the basal temperature is thus lowered.

20 The action of progesterone results in contraction of the skin vessels by way of vegetative diencephalon centres. Heat radiation and conduction are thereby decreased and the body temperature rises.

On account of the large storage capacity of the
25 tissue, the change in the internal body temperature is very slow, whereas the skin temperature reacts immediately.

Although measurement of the skin temperature provides the greatest variations during the course of
30 the day, hormone-related temperature changes can nevertheless be recorded very much earlier.

4. Method for determining ovulation

If an electronic wrist watch with in-built
35 temperature measurement of the skin (wrist) is worn constantly, the temperature will be measured via the in-built microprocessor only at a clearly predetermined time. To ensure that all disruptive factors such as

stress, food intake etc. are avoided, the measurement takes place shortly before waking, e.g. at 6 a.m.

5 The measurement time is individually programmed so that the resting temperature of the subject wearing the wrist watch is always determined automatically at the same time before waking. A large number of individual measurements are taken over a period of 5 to 15 minutes and a mean value is derived from these. This value is stored and compared with the value from the previous day. If these values agree, no further measurement is made, and the value remains stored. However, if deviations are recorded, the measurement is repeated. If the first value is confirmed, the difference from the previous day is stored and recorded indicating the trend with + or -.

The microprocessor additionally contains the programmed normal cycle duration of the subject wearing the wrist watch, with the previously most common time for ovulation.

20 These data are initially estimated, but are later confirmed and substantiated by the large number of individual measurements. This provides a time period of critical days within the confirmed cycle. Each individual value is classified with the index of its sequence in this matrix. If, on the next day, a further value is found which is once again lower than that of the previous day, and if in addition the measurement period falls within the critical area of 5 - 4 days about the average ovulation, a first warning is signalled.

30 A further drop or a drastic rise in the temperature is evidence of ovulation having already started, and a corresponding recommendation is output.

35 The advantage of measuring the temperature of the skin is that the minimum temperature is already measured 24 hours before ovulation (at the same time as the oestrogen maximum), whereas the internal body temperature only reaches the minimum at the time of ovulation.

After ovulation, the egg is only fertilizable for 6 - 12 hours, whereas the sperm are viable for up to 72 hours.

5 The microprocessor takes these natural factors into account too and, thus informed, formulates its recommendation in good time according to the predetermined objective.

10 For preventing pregnancy, a greater safety interval should be built in at the start according to the variance of the times. With an increasing number of findings over the period of ovulation, the interval becomes smaller, finally ending 3 days before ovulation. Together with an additional safety day, the time for fertilization drops to 4 days. By refraining
15 from sexual intercourse in these critical but temporally narrowly fixed phases, safe contraception without chemical or mechanical means is made possible. In addition, this type of contraception is also acceptable to those holding very strong religious
20 beliefs.

For regulating pregnancy, this method is even more reliable since the most favourable time for fertilization lies between temperature minimum and temperature rise.

25 Planned children are very easy to conceive using this temperature measurement method, provided that the other conditions are satisfied.

The stored temperature data can be traced back for up to 4 days and can be called up at the touch of a
30 button.

The temperature curves can be very easily shown graphically on forms, thereby giving a clear illustration of the actual temperature profile. The date of ovulation determined per cycle is automatically
35 included in the updated statistical evaluation. This permits continuous correction of the mean date and a sliding calculation of the standard deviation, as a measure of the range of variation of the dates.

If pathological temperature variations occur, e.g. fever, or other rhythm disturbances, this irregularity is also signalled. If the date of ovulation cannot be reliably determined on account of this, this finding is dropped from the updating. The warning during the critical phase is unaffected by this but definite.

With this very early detection of temperature anomalies, the physician can also begin treatment at a very early stage.

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Annex to Patent
Application of
[illegible]

PATENT CLAIMS

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1. Method for use in women capable of bearing children for determining fertile days from early detection of ovulation, by means of automatic temperature measurement, characterized in that the temperature of the skin, e.g. at the wrist, is measured using a wrist watch which contains a temperature measurement facility which evaluates only the measured values at clearly specified times of the day, preferably between 5 and 7 a.m., and automatically such that the respective daily values are compared and, if there is a significant and constant increase following a preceding fall in temperature, a corresponding recommendation signal is delivered which, depending on the objective, can signify: abstinence for 3 - 5 days, or optimum fertilization period.

2. Method according to Claim 1, characterized in that the measurement of the skin temperature takes place automatically at an individually selectable, fixedly set time before waking, and in such a way that a representative mean is formed from a multiplicity of individual measurements within a preselected total measurement period of 5 to 15 minutes and is correspondingly stored.

3. Method according to Claims 1 and 2, characterized in that the daily value thus determined is compared with the values from the previous three days and, if there is a constant increase within the range of a few tenths of a degree Celsius, this is a significant indicator of the onset of ovulation.

4. Method according to Claims 1 to 3, characterized in that the skin temperature is measured

which although in absolute terms lower than the basal temperature because of the physiological temperature-regulating mechanisms of the body can be measured very much earlier than in basal temperature measurements -
5 up to 24 hours - the temperature minimum can be measured at the same time as ovulation.

5. Method according to Claims 1 to 4, characterized in that, by suitable programming of the electronic wrist watch with in-built temperature
10 measurement facility, pathological temperature anomalies, such as fever, etc., are recognized as such and signalled and do not disturb the ovulation detection program.

6. Method according to Claims 1 to 5,
15 characterized in that the ovulation time determined in each case is automatically stored and thus narrows the period more and more, with increasingly greater statistical expressiveness from cycle to cycle, and thus a critical period for ovulation is determined
20 which comprises only a few days.

7. Device according to Claim 1, characterized in that a fully electronic wrist watch is equipped with a temperature sensor, a temperature measurement facility, a microprocessor for recording and processing of
25 measurement data, and a display device for outputting acoustic and/or optical signals, and it is therefore able to determine ovulation in women capable of bearing children and can thus be used as an instrument for birth control.

30 8. Device according to Claims 1 to 7, characterized in that the last 4 average daily temperatures stored can be called up in each case, thereby permitting a graphic illustration of the temperature course.

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Hammah, 17.12.82

[signed]

Abstract

Fully electronic wrist watch with temperature measurement facility for family planning

The timing method described by Knaus and Ogino for periodic abstinence is modified by this automatic measurement of the skin temperature in such a way that a more reliable method of contraception is thereby afforded.

The period of sexual abstinence is shortened so that this method is reasonable and acceptable - 5 days instead of 10 days with Knaus-Ogino.

The greatest advantage is achieved in cases where children are wanted, because with more exact knowledge of ovulation the few available hours of possible fertilization can be optimally utilized.

Irregularities in the temperature profile are very quickly detected and represent an excellent diagnostic aid for the treating physician.

All in all, this proposed wrist watch offers an aid to allowing millions of women to achieve their longed-for aim of becoming mothers, and it additionally contributes to slowing the worldwide population explosion.